Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1-21. (Cancelled)

22. (New) A pharmacologically active combination, having utility in treating insomnia patients, which comprises:

(a) at least one first active ingredient selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; and

(b) at least one second active ingredient selected from nicotine and nicotine receptor agonists.

23. (New) A pharmacologically active combination according to claim 22, which is characterized by at least one of the following features:

(i) it comprises also at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and said dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier and/or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

24. (New) A pharmacologically active combination according to claim 23, which is in said form of dosage units, wherein each dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025-100 mg.

25. (New) A pharmacologically active combination according to claim 24, wherein said amount lies within the range of 0.25 to 50 mg.

26. (New) A pharmacologically active combination according to claim 25, wherein said amount lies within the range of 0.5 to 40 mg.

27. (New) A method of treating a patient in the course of nicotine replacement therapy for the purpose of alleviating at least one adverse effect occurring in the patient, said adverse effect selected from the group consisting of impairment of sleep quality, impairment of cognition and impairment of memory; said method comprising the administration to said patient of a first medicament comprising at least one active ingredient (a) selected from the group consisting of melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; wherein said patient optionally is receiving simultaneously a second medicament comprising a second active ingredient (b) selected from the group consisting of nicotine and nicotine receptor agonists.

28. (New) The method according to claim 27, wherein each of said medicaments is characterized respectively by at least one of the following features:

(i) it further comprises at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and said dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled sustained or prolonged release formulation;

(iv) it is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

29. (New) The method according to claim 28, wherein each of said first and second medicaments is in the form of dosage units, wherein each said dosage unit contains at least one of said active ingredients in an amount which lies within the range of 0.025 - 100 mg.

30. (New) The method of claim 29, wherein said amount lies within the range of 0.25 - 50 mg.

31. (New) The method of claim 30, wherein said amount lies within the range of 0.5 - 40 mg.

32. (New) A method of treating a patient for the purpose of alleviating at least one adverse effect occurring in said patient, said adverse effect selected from the group consisting of impairment of sleep quality, impairment of cognition and impairment of memory; said method comprising the administration to said patient of a first medicament comprising at least one active ingredient (a) selected from the group consisting of melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; wherein said patient optionally is receiving simultaneously a second medicament comprising a second active ingredient (b) selected from the group consisting of nicotine and nicotine receptor agonists.

33. (New) The method of claim 32, wherein each of said medicaments is characterized by at least one of the following features:

(i) it further comprises at least one diluent, carrier or adjuvant;

(ii) it is in the form of dosage units, and said dosage units are adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration;

(iii) it is a controlled, sustained or prolonged release formulation;

(iv) it is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;

(v) said ingredient (a) is melatonin;

(vi) said ingredient (b) is nicotine;

(vii) it comprises at least one melatonin receptor modifier or melatonin profile modifier;

(viii) said first and second active ingredients (a) and (b) are formulated in a single formulation.

34. (New) The method of claim 33, wherein said first and second medicaments respectively are in dosage unit form, wherein each of said dosage units contains at least one of said active ingredients in an amount which lies within the range of 0.025 - 100 mg.

35. (New) The method of claim 34, wherein said amount lies within the range of 0.25 - 50 mg.

36. (New) The method of claim 35, wherein said amount lies within the range of 0.5 - 40 mg.

37. (New) A kit having utility in treating insomnia patients, which comprises:

(A) a first pharmaceutical formulation in unit dosage form comprising, in addition to at least one diluent, carrier or adjuvant, at least one first active ingredient selected from melatonin, other melatonergic agents, melatonin agonists and melatonin antagonists; and

(B) a second pharmaceutical formulation in unit dosage form comprising, in addition to at least one diluent, carrier or adjuvant, at least one second active ingredient selected from nicotine and nicotine receptor agonists;

wherein the dosage units in (A) and (B) are independently selected from those adapted for oral, rectal, parenteral, transbuccal, intrapulmonary or transdermal administration.

38. (New) A kit according to claim 37, which is further characterized by at least one of the following features:

(i) at least one of (A) and (B) is a controlled, sustained or prolonged release formulation;

(ii) at least one of (A) and (B) is in a depot form which will release said active ingredients slowly in the body, over a preselected time period;

(iii) said at least one first active ingredient comprises melatonin;

(iv) said at least one second active ingredient comprises nicotine;

(v) (A) comprises also at least one melatonin receptor modifier and/or melatonin profile modifier;

(vi) (A) comprises also at least one further active ingredient selected from nicotine and nicotine receptor agonists;

(vii) said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.025-100 mg.

39. (New) A kit according to claim 38, wherein said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.25 to 50 mg.

40. (New) A kit according to claim 39, wherein said first and second active ingredients, and said further active ingredient if present, are present in said dosage units in an amount which lies within the range of 0.5 to 40 mg.

41. (New) A kit according to claim 37, wherein (A) and (B) are each in the form of a transdermal patch.

42. (New) A kit according to claim 37, wherein (A) is in the form of a controlled release tablet for oral administration and (B) is in the form of a transdermal patch.